PHP90
RELATIONSHIP BETWEEN THE DEVELOPMENT OF ELECTRONIC HEALTH RECORDS AND HOSPITAL ACCREDITATION DECISIONS IN FRANCE: RESULTS FROM THE E-SI (PREPS-SIPS) STUDY
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OBJECTIVES: To make eHealth technology more efficient, particularly for the quality and safety of care, the French Ministry of Health (DGOS) launched the national "Hopital numérique 2012-2017" program, a strategic development plan for the modernization of health information technology. The aim of this study was to assess the impact of the development of electronic health records (EHR) on the accreditation results of French hospitals performed by the HAS (French National Authority for Health). **METHODS:** This retrospective study included all of the acute care hospitals accredited between October 2012 and April 2014. Three national databases were used: national accreditation database, oSIS (observatoire des systèmes d'information de santé-2012), and IPAQSS (indicateurs pour l'amélioration de la qualité et la sécurité des soins-2012). National data were provided by the DGOS and HAS, together with methodological support. We developed an ordered Logit model, where the polytomous dependent variable was ordered according to the following descriptions: full accreditation, recommendation, reservation, or delay in the accreditation decision. The independent variables were the proportion of EHR used (full, partial, or no EHR); type of hospital (teaching, private non-profit, for-profit, or other public hospital); accuracy of the care, with versus without home care hospitalization; and geographic region. **RESULTS:** The study included 679 hospitals; 21% had full accreditation, 45% recommendation, 25% reservation, and 9% a delay in accreditation. We found that the higher the number of full EHR used, the better the accreditation decision ($p<0.001$). We also observed that the higher the number of partial EHR used, the better the accreditation decision ($p=0.002$). Finally, the accreditation decision was also better for for-profit hospitals ($p<0.001$), private non-profit hospitals ($p=0.005$), and in the southeast of France ($p=0.02$). **CONCLUSIONS:** Our findings suggest that the development of EHR in acute care hospitals is associated with a higher performance in accreditation decisions in France.

PHP92
SERIOUS ADVERSE DRUG EVENTS REPORTED TO THE FOOD AND DRUG ADMINISTRATION (FDA): ANALYSIS OF THE FDA ADVERSE EVENT REPORTING SYSTEM (FAERS) 2006-2011 DATABASE
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OBJECTIVES: In 1998, the Food and Drug Administration (FDA) Adverse Event Reporting System (FAERS) (formerly AERS) was launched by the FDA as a post-marketing safety surveillance program to capture adverse drug events (ADEs) and medication errors. From 1998 to 2005, it was found that the number of serious and fatal ADEs reported to the FDA increased by 2.6-fold and 2.7-fold, respectively. The purpose of this study was to document current trends in serious and fatal ADE reports. **METHODS:** We conducted a retrospective analysis of the 2006-2011 FAERS database. Information on patient demographics, primary suspect drug, outcomes, and other variables were obtained from data files. Non-US reports and reports from clinical trials were excluded. Outcomes were recoded into three categories: death, disability (disability or congenital anomaly), and all other serious outcomes (hospitalizations, requiring intervention, or life-threatening, or other serious outcomes). We determined the number of reports by year, the types and sources of reports, and age-wise distribution of serious ADEs. A list of drugs with more than 1,000 reports of serious ADEs was compiled and subgroups of important drugs were identified **RESULTS:** A total of 245,265 reports of deaths (53,447), disabilities (20,305), and other serious outcomes (171,513) were reported representing 206,087 person-reports. The percentage of reports involving death increased from 17.3% in 2006 to 27.0% in 2011. Analgesics, antihypertensives, and antipsychotics were the most common drugs involved in serious reports of ADEs. Drugs with more than 1,000 serious reports of ADEs included 2 drugs currently withdrawn from market, 4 drugs under the FDA Risk Evaluation and Mitigation Strategies (REMS) program, 11 specialty drugs, 3 biologic drugs, and others. **CONCLUSIONS:** A substantial number of serious ADEs were reported from 2006-2011. Drugs under the REMS program, specialty drugs, and biologic drugs contribute to a significant number of serious ADEs.

PHP93
SENSITIVITY, SPECIFICITY AND LEVEL OF AGREEMENT BETWEEN DIFFERENT CRITERIA USED TO DIAGNOSE THE METABOLIC SYNDROME
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OBJECTIVES: Numerous diagnostic criteria of the metabolic syndrome exist including the recent 2009 World Health Organization definition, criteria for National Cholesterol Education Program Adult Treatment Panel III (NCEP-ATP III), International Diabetes Federation (IDF) and European Group for Study of Insulin Resistance (EGIR). The multiplicity of definitions makes comparing studies with older criteria difficult. Our objective was to compute sensitivity, specificity, positive (PPV) and negative predictive values (NPV) and level of agreement between WHO standard and other definitions to determine which criteria performs best when comparing estimates from previous studies. **METHODS:** The NHANES 2009-10 and 2011-2012 demographics, examination and laboratory data formed our cohort. Prevalence estimates using all criteria were calculated. Sensitivity, specificity, PPV and NPV of all criteria keeping the WHO criteria as gold standard were computed. Kappa statistics to determine strength of agreement between WHO criteria relative to other definitions were estimated. **RESULTS:** WHO criteria yielded the highest prevalence at 22.2% followed by NCEP (19.1%), IDF (9.8%) and EU criteria (6.2%). Sensitivity of the NCEP criteria was the highest at 86.2% followed by IDF (38.6%) and EU (25.9%) criteria. Specificity of the NCEP criteria was highest at 100% followed by EU (99.3%) and IDF (98.3%) criteria. The PPV of the NCEP criteria was 100% while those of EU and IDF criteria were 91.8% and 86.9% respectively. Similarly the NPV was highest for the NCEP criteria followed by the EU (99.3%) and IDF (98.3%) criteria. The kappa-statistics showed highest agreement with the NCEP criteria (kappa=0.90) while the IDF (kappa=0.46) and EU criteria (kappa=0.33) displayed moderate and fair levels of agreement respectively with the WHO criteria. **CONCLUSIONS:** Our findings demonstrate that NCEP criteria displayed best performance parameters relative to WHO criteria and may serve as alternative to the WHO criteria when comparing other definitions used in older studies to current studies.

PHP94
IN THEIR OWN WORDS: SOCIAL LISTENING FOR "REAL-WORLD BENEFITS" FROM PRESCRIPTION AND OTC PRODUCTS
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OBJECTIVES: The objective of this study was to evaluate "real-world benefit" discussions from publically available de-identified sources (social media and internet forums) that can be obtained through social listening. **METHODS:** A third party vendor collected posts from Facebook and Twitter over the previous year for a variety of 15 prescription and over-the-counter (OTC) products. Data vocabularies were standardized using a vernacular to MedDRA dictionary for medical conditions and a custom curated vernacular dictionary for drugs and OTC products. Next, noise was systematically removed via natural language processing and each post was characterized as a Mention (drug mentioned but no adverse events) or a Proto AEs (potential adverse event mentioned within the context of drug use). Finally, the data was de-identified prior to making it available to the research team who then manually reviewed each post and collected "real-world benefit" attributes. **RESULTS:** Overall 2159/7529 (29%) of Mentions and Proto AEs contained "real-world benefit" information; of the 2159 posts, 1207 (56%) were positive benefits discussions and 952 (44 %) discussed lack of effect. Of the positive benefits discussions (N=1207), 94 (8%) contained benefit time-to-onset, 28 (2%) contained duration of benefit, 125 (10%) indicated partial benefit, 514 (43%) indicated full benefit, 37 (3%) contained benefits discussion within the context of cost, 196 (16%) contained benefits discussion within the context of adverse events, and 138 (11%) contained benefits information as compared to other treatment options. **CONCLUSIONS:** Social listening has the potential to provide a large amount of information about "real-world benefit" as discussed from the consumers'/patients' perspective. This is the first step in understanding how Social Listening can contribute to better characterization of benefit/risk profiles using the consumers' own voice.

PHP95
IS THERE AN ASSOCIATION BETWEEN POTENTIALLY INAPPROPRIATE PRESCRIBING IN THE ELDERLY AND HOSPITALIZATION AND MORTALITY? A LONGITUDINAL, LARGE COHORT STUDY
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OBJECTIVES: Prevalence of potentially inappropriate prescribing (PIP) of harmful medications in the elderly has been widely investigated, but it remains unclear whether PIP is predictive of adverse events. Our study objective was to determine whether exposure to PIP is linked to increased rates of hospitalization and mortality. **METHODS:** We performed a retrospective analysis using the Italian Regione Emilia-Romagna (RER) longitudinal administrative healthcare database of all elderly patients ($\geq$ 65 years) from 2003 to 2013. The RER database includes de-identified, fully-linkable demographic, hospital, and pharmacy claims data for all residents in the region. PIP exposure initiated upon the dispensing of a medication that "should always be avoided" based on the Maio criteria. To estimate PIP exposure we computed the number of days supplied for each medication of interest (using Defined Daily Doses) plus 30 days. An exposure period spanned the duration of consecutive PIP dispensings. An event, the composite outcome of hospitalization or death, was attributed to PIP if it occurred during an exposure period. Rate ratios and 95% confidence intervals (CI) were estimated by Poisson generalized estimating equations modeling. **RESULTS:** The 1,471,179 elderly individuals living in the RER contributed a total of 10,369,120 person-years (PY) of follow-up time and experienced a total of 1,973,878 events. The unadjusted event rate was 1.572 (95% CI: 1.562, 1.580) times greater among patients exposed to PIP compared to those not exposed (2.87 events/10 PY vs. 1.82 events/10 PY). The unadjusted mortality rate was 1.473 (95% CI: 1.458, 1.488) times greater with PIP exposure (0.51/10 PY vs. 0.35/10 PY). **CONCLUSIONS:** These results indicate that exposure to PIP may be associated with higher hospitalization and mortality rates in elderly patients. This analysis, using a large cohort of patients, sheds light on the importance of reducing PIP in this population.

PHP96
AN INTENSIVE STUDY OF ADVERSE EVENTS IN THE MEDICAL UNIT OF A NIGERIAN TEACHING HOSPITAL
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OBJECTIVES: Adverse Events (AEs) has proven to be a significant cause of hospital admissions, with prevalence rate ranging from 6.5-26.1% and this constitute a significant problem with serious consequences and a challenge for public health. This intensive study is aimed at determining the prevalence of AEsas well as to assess the cause, nature, severity, preventability and outcomes in a Nigerian teaching hospital and to determine the class of suspected drugs most commonly implicated. **METHODS:** A three months observational study of 221 consecutive adult patients of the Lagos University Teaching Hospital medical in-patient ward and out-patient clinic. Epi-info statistical software, (Version 3.4.3, 2007) was used to analyze and determine prevalence, causality, severity and preventability. A significance level of $p < 0.05$ was used. **RESULTS:** The prevalence of AEs was 17.6% (95% CI; 12.9, 23.3) with 30 (79.5%) of these presenting at admission and 8(20.5%) developing during hospitalization. The World Health Organization (WHO) causality

assessment ranking showed that 46.2% of AEs were classified as probable, 35.9% possible and 7.9% certain. Based on severity of the AEs, 59.0% were classified as moderate 30.8% severe, 5.1% mild and lethal respectively. 87.2% of the AEs were assessed as possibly preventable. Assessment of outcomes showed that 94.9% of the patients recovered fully while 5.1% died. The organs/systems mostly involved in the adverse events were the CNS (headache, dizziness and body pain, 22.1%), cutaneous organ (rashes and itching, 19.6%) and respiratory system (Breathlessness and cough, 13.5%) Antihypertensives (76.8%), antibiotics (10%), antiretrovirals (7.7%) and cholesterol lowering agents (7.7%) were the most commonly implicated classes of drugs. **CONCLUSIONS:** The study shows that AEs constitute a significant cause of hospital admissions and a good number will likely develop during hospitalization. Intensive monitoring and evaluation of AEs is feasible and will likely provide a clearer picture of clinical outcomes.

PHP97

RACIAL/ETHNIC DISPARITIES IN DISABILITY PREVALENCE

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OBJECTIVES: Worldwide, the number of disabled individuals is used as a marker for population health status because of high morbidity and mortality burden associated with disability. Prior studies, which analyzed racial/ethnic disparities in individuals with disability, have limitations in regards to population, scope or were limited to individuals with chronic condition. The purpose of this study is to determine prevalence of disability in different racial/ethnic groups using a standard framework for disability. **METHODS:** A retrospective cross-sectional study design with data from 7,993 individuals aged above 21 years from 2012 National Health Interview Survey (NHIS) was adopted. Race/ethnicity was categorized into: 1) White; 2) African American; 3) Latino and 4) other. Disability was defined based on a standard set of questions about mobility, self-care, and cognition from the "Functioning and Disability" supplement of 2012 NHIS and it was grouped as: 1) No disability; 2) Moderate disability; and 3) Severe disability. Chi-square tests and multinomial logistic regressions were conducted to examine the association between race/ethnicity and disability. **RESULTS:** There were statistically significant racial/ethnic differences in disability status; 10.2% Whites, 14.8% African Americans, 8.1% Latino, and 6.7% other racial minorities had severe disability. Without adjustments for socio-economic status, African Americans were more likely to have severe disability than Whites (AOR=1.56, 95% CI=1.24, 1.95) and Latinos were less likely to have severe disability (AOR = 0.70, 95% CI=0.55, 0.90). After adjusting for socio-economic status, we did not observe statistically significant differences in disability status among African Americans and Whites. After adjusting for presence of chronic conditions, statistically significant differences in disability status among Latinos and Whites disappeared. **CONCLUSIONS:** Differences in prevalence of disability between African Americans and Whites can be partially explained by low socio-economic status of African Americans. Improving socio-economic status of African Americans may reduce racial disparities in disability prevalence.

PHP98

COMPARATIVE EFFECTIVENESS RESEARCH (CER) AND ITS EFFECT ON THE HEALTH CARE DECISION-MAKING ENVIRONMENT

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OBJECTIVES: Track the perceptions of key CER stakeholders about the current and future effects of CER on evidence generation and application for health care decisions **METHODS:** Internet and mail survey of health care stakeholders, including government, health plans, researchers, human resources specialists, employers, and trade organizations, that are influential in or affected by CER; telephone follow-up to maximize response. **RESULTS:** Two-thirds of CER stakeholders say that the current CER evidence base is insufficient to support treatment decisions, but 90 percent remain committed to the importance of CER. This fifth survey in a series begun in 2010 found fewer respondents reporting no short-term effects of CER, but more than half of respondents believe that substantial improvement in decision-making based on CER will occur over the next 5 years. Almost three-fourths of respondents recognize PCORI's significance in funding and monitoring new research, nearly double the level five years ago. Respondents are more positive about research priorities; nearly 40 percent believe priorities somewhat/adequately reflect treatment choices faced by patients and providers, compared to only 22 percent two years ago. Just 9 percent believe that processes for interpreting evidence are fully transparent and objective, fewer than in the previous three surveys. Only about 25% of respondents report that real-world evidence or evidence about variability in individual patient response is being used to support treatment decisions. **CONCLUSIONS:** In successive surveys, CER stakeholders continue to look to a five-year horizon for significant effects from CER. They generally view the evidence base as incomplete, recognize the key players in generating new evidence, and understand the time needed for research in their projections of CER's impact. The relatively scarce use of real-world evidence and evidence about patient variability reflects their views about the completeness of the evidence base to support treatment decisions.

PHP99

EMERGENCY DISEASE SPECTRUM IN CHINA: BASED ON HOSPITAL DATABASE FROM BEIJING

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OBJECTIVES: This study is to analyze age, disease category, time of emergency treatment and regularity of visiting doctors in order to realize the distribution of disease spectrum and epidemiological analysis in emergency department in the top three hospital in China. **METHODS:** To select 29,654 cases in emergency department of hospital database of 2013. The top five emergency diseases were studied by retrospective research. Data analysis was performed with STATA software package. ncy department in the top three hospital in China. **RESULTS:** The majority of the emergency cases were young people under 40 years old. Male patients (53.9%) were more than female patients. The frequency of emergency visit is 2.7 average per year, male patients get 3.0 visits more than female 2.4 visits. About 33.9% of patients at one's own expense. Diseases in the top five were respiratory disease, trauma, digestive system diseases, circulation system disease, urinary diseases, respectively. Respiratory disease was the leading member in the spectrum, accounting for 25.5%. Poisoning patients account for 1.6% of all emergency cases. Wounded patients mostly centralized from May to August, and the bottom periods of the treatment time appeared in midnight (0:00 – 6:00), accounting for 5.5%. **CONCLUSIONS:** Composition of emergency disease spectrum and characteristics of time distribution can help to develop new prevention and treatment strategies for improving quality and increase efficiency. The treatment for respiratory disease headed the list of emergency disease spectrum need to optimize medical resourse utilization and process improvement.

PHP100

KEY TRENDS IN HEALTHCARE SPENDING IN BRAZIL IN 2015

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OBJECTIVES: To identify the key trends in healthcare spending in Brazil in 2015. **METHODS:** Review of the Ministry of Health (for programs), Ministry of Planning (for budget) and Workd Bank (for GDP growth) reports as well as recently published financial information on Bloomberg and Valor (Brazilian newspaper) on Federal and States spending. **RESULTS:** The economic program established by the Brazilian government forecasts growth will return only in 2016. It is worth remembering that in 2014 the GDP growth in Brazil was very close to nil. In 2015, economists expect the GDP increase to be below 1%. The Ministry of Health budget in 2014 was US$ 45.6 billion vs. 2015: US 41.2 billion, a 9.6% reduction caused by increased inflation and the devaluation of the Brazilian real against the American dollar. Moreover, with the reduction in the price of oil some states, such as Rio de Janeiro, might lose US$ 750 million in royalties. In the private setting, ANS, the Federal agency that regulates private payers (HMOS, healthcare insurers, etc.), is getting ready this year to work on the update of the Minimum Mandatory Coverage List valid January 2016 on. In a sector in which 80% of the health plans are either collective (unions) or paid by companies, thus, dependent on the expansion of the economy, the willingness to pay for the incorporation of new technologies would probably be low. **CONCLUSIONS:** With a struggling economy ahead and consequently smaller budgets, not only does the Federal Government foresee adjustments in public spending but also do State Governments. Context indicates that dialogue and flexibility among healthcare players will be needed more than ever.

PHP101

COMPARATIVE EFFECTIVENESS, APPROVAL RATES AND PRICING OF DRUGS WITH FDA'S BREAKTHROUGH THERAPY DESIGNATIONS

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OBJECTIVES: In 2012, the United States Food and Drug Administration (FDA) created a new expedited pathway of "Breakthrough Therapy Designation" (BTD) to enable an early approval of therapies which have shown substantial activity in early trials. The objective of this study was to assess the comparative effectiveness and pricing of drugs with BTD. **METHODS:** The data for the number of granted BTDs was obtained from FDA.gov. The data for publically disclosed BTDs was obtained from sponsor's press releases. For all products, the information for their mechanism of action, type of molecule, trial design, clinical efficacy and safety, and pricing and time to approval (for approved products) were obtained from peer-reviewed publications, conference abstracts, FDA and sponsor websites. **RESULTS:** Since the establishment of the BTD pathway, 55 products have been granted breakthrough therapy designations (2012-2014), of which, 42 have been publically disclosed by the manufacturers and 6 have been approved by the FDA. In terms of indications, 43% are for cancer, 18% are for genetic diseases and 14% are for Hepatitis C Genotype 1. The median time to approval for these three drug was ~5 years, significantly shorter than the 2012 median time to approval for priority review applications (6 years). The price premium was 30-50%, compared to other drugs in the same category. The six approved BTDs show 20-30% higher response rates than other products in the same category. The other products in the pipeline with established comparators show 36%-136% improvement in efficacy (based on active controls or previous trials). For approximately half of the products, comparative efficacy cannot be determined because of no previous evidence for a product with efficacy in the targeted indications. **CONCLUSIONS:** BTD is a promising pathway to shorten development time and provides early access, however, the high price could pose challenges for payers and patients.

PHP102

THE VALUE OF OTC MEDICINES IN BRAZILIAN PUBLIC HEALTH SYSTEM (SUS)

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OBJECTIVES: Demonstrate possible savings by expanding the responsible use of OTCs (over-the-counter or nonprescription drugs) in Brazil in the public perspective. **METHODS:** Measure the volume and medical costs on public health system emergency and usage of OTC medicines. Data were obtained from the DATASUS system (030106006), SIGTAP 3.01.1.1.3, and research CHPA / USA January 2012 and adopted the premise of 10% OTC in the treatment of common diseases (common flu, allergy, and pain), to identify the average ticket cost on OTC consumption were used IMS Health of 2013 data and for absenteeism costs were used the Brazilian Ministry of work and IBGE data. **RESULTS:** It was estimated that 8% (5,101,692) of all emergency attendances in SUS 2013 resulted in prescriptions that exhibited OTC medicines to treat common diseases, at a cost of 56 million,costs related to improductible days at BRL 369 million and expenditure in the acquisition of these